

Statement of March 5, 2001 which were purportedly missing from Exhibit A.

Additionally, as requested by the Examiner, enclosed are copies of claims of the co-pending applications recited in the Information Disclosure Statement filed on March 5, 2001.

**II. Figure 11**

With respect to the Examiner's request for clarification regarding Figure 11, enclosed is a copy of the figure previously sent to the United States Patent Office with the Preliminary Amendment of July 24, 2000, and which will now be considered Figure 10 in accordance with the Preliminary Amendment of July 24, 2000. Additionally, applicants are submitting herewith a submission of formal drawings, which includes all of the figures present in the application.

**III. Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 13-16 were rejected under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention." Specifically, the Examiner refers to claim 13 and states that "protein-'derived' materials are indefinite since the expression does not define the structures contemplated with a reasonable degree of particularity."

*maintain*  
In response, it is respectfully submitted that one of ordinary skill in the art would understand the meaning of the term protein-"derived" materials when referring to polymers. It is respectfully submitted that polymers which are protein-"derived" materials are known in the art. It is therefore respectfully requested that the 35 U.S.C. § 112 rejection be withdrawn.

**IV. Non-Statutory Double Patenting Rejections**

Claims 6-23 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,478,577 as well as

over claims 1-14 of U.S. Patent No. 5,672,360.

With regard to U.S. Patent Nos. 5,475,577 and 5,672,360 applicants note that the claims of these patents fail, at the very least, to recite or suggest the following limitations of claim 6 of the present application:

- A. wherein the dissolution rate in-vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 ml aqueous buffer at pH 1.6 and 7.2 and at 37 °C is from about 12.5% to about 42.5% (by wt) opioid released after 1 hour, from about 25% to about 65% (by wt) opioid released after 2 hours, from about 45% to about 85% (by wt) opioid released after 4 hours and greater than 60% (by wt) opioid released after 8 hours,
- B. the in-vitro release rate being substantially independent of pH in that a difference, at any given time, between an amount of opioid released at one pH and an amount released at any other pH, when measured in-vitro using the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm in 900 ml aqueous buffer is no greater than 10%,

On this basis, applicants respectfully request that the Examiner's double patenting rejection based upon the 5,475,577 and 5,672,360 patents be withdrawn. Accordingly, no terminal disclaimer is being submitted with this Amendment.

#### **V. Conclusion**

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn. It is believed that all pending claims are now in a condition for allowance.

The Examiner is invited to contact the undersigned at the telephone number provided below if it is determined that any further issues remain.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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Figure 11/10

